

ALLOY Data

BioDur® 108 Alloy

Identification

UNS Number

• S29108

Type Analysis

Carbon (Maximum)	0.08 %	Manganese	21.00 to 24.00 %
Phosphorus (Maximum)	0.030 %	Sulfur (Maximum)	0.010 %
Silicon (Maximum)	0.75 %	Chromium	19.00 to 23.00 %
Nickel (Maximum)	0.10 %	Molybdenum	0.50 to 1.50 %
Copper (Maximum)	0.25 %	Nitrogen (Minimum)	0.90 %
Iron	Balance		

0.05% max nickel available upon request

General Information

Description

BioDur® 108 alloy is an essentially nickel-free austenitic stainless alloy. The alloy contains a high nitrogen content to maintain its austenitic structure. As a result, BioDur 108 alloy has improved levels of tensile and fatigue strength, as compared to nickel-containing alloys such as Type 316L (ASTM F138), 22Cr-13Ni-5Mn alloy (ASTM F1314), and 734 alloy (ASTM F1586). The resistance of BioDur 108 alloy to pitting and crevice corrosion is superior to Type 316L alloy and equivalent to the 22Cr-13Ni-5Mn and 734 alloys. BioDur 108 alloy is produced by the Electro-Slag Remelting (ESR) process to assure its microstructural integrity and cleanliness. The alloy is non-magnetic and essentially free of ferrite phase.

Applications

BioDur 108 alloy should be considered for use in applications requiring high levels of strength and corrosion resistance. This alloy should be considered a potential candidate for implantable orthopedic applications such as bone plates, bone screws, spinal fixation components, hip and knee components, hypoallergenic jewelry, orthodontic appliances, and other medical components and instruments fabricated by forging and machining.

Disclaimer:

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Biocompatibility Summary

Cytotoxicity

A study was conducted based on the procedure described in ANSI/AAMI/ISO 10993-5:1993; Biological evaluation of medical devices - Part 5: tests for cytotoxicity. The BioDur 108 alloy test article was concluded to be non-cytotoxic and meeting the requirements of the Elution Test, ISO 10993.

Irritation

Testing was based upon ISO Biological Testing of Medical Devices Part 10: Irritation and Sensitization Tests, ISO 10993-10,1995. Extraction procedures were based upon ISO 10993-12, 1996. The test sites did not exhibit any signs of erythema, edema or necrosis and the BioDur 108 alloy test article was concluded to be a negligible irritant.

Acute Systemic Toxicity

Testing was based on ISO Biological Evaluation of Medical Devices - Part 11:

Tests for Systemic Toxicity, ISO 10993-11,1993. Extraction procedures were based upon ISO 10993-12, 1996. No signs of toxicity were observed and the test article was concluded to meet the requirements of ISO 10993-11, Systemic Injection Test.

Pyrogenicity

Testing was based on ISO Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity, ISO 10993-11,1993, and upon the standards set by the current version of the United States Pharmacopia. Extraction procedures were based upon ISO 10993-12, 1996. The BioDur 108 alloy test article was concluded to meet the requirements of ISO 10993-11 for the absence of pyrogens as specified for the Pyrogen Test.

Mutagenicity

Testing was based on ISO Biological Evaluation of Medical Devices, Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity; ISO 10993-3, 1992, and revised methods for the Salmonella Mutagenicity test, Maron, D.M. Ames, B.N., Mutation Research, 113:173-215, (1993). Extraction procedures were based upon ISO 10993-12,1996. The BioDur 108 alloy test article was concluded to be non-mutagenic based on the methods employed.

Implantation With Histopathology

Testing was based on ANSI/AAMI/ISO 10993-6:1995; Biological Testing of Medical Devices, Part 6: Tests for Local Effects After Implantation; and ASTM Standards Section 13, Volume 13.01, Medical Devices, Designation: F 981-93 (1996). No signs of toxicity were exhibited after 14 and 28 day implantation test periods and the BioDur 108 alloy test article was concluded to be non-toxic.

Hemocompatibility

Testing was based on the following references: DHEW publication # (NIH) 77-1294, 9.213,1977; ISO Biological Evaluation of Medical Devices, Part 4, Selection of Tests for Interactions with Blood, ISO 10993-4 1992; Extraction Procedures were based on ISO 10993-12,1996; Autian Method described in ATTP-I, University of Tennessee Center for the Health Sciences, Memphis, TN, 18-Apr-77; Veterinary Hematology, Schalm O.W., pp 51-53,1965, Lea & Feviger, Philadelphia. The BioDur 108 alloy test article was concluded to be non-hemolytic based on the methods employed.

Testing was conducted and reported by Toxikon Corporation, 15 Wiggins Avenue, Bedford, MA 01730, USA, on behalf of Carpenter Technology Corporation.

Corrosion Resistance

BioDur 108 alloy possesses a high resistance to corrosion due to its high levels of chromium and nitrogen and its molybdenum content. The alloy exhibits excellent resistance to pitting and crevice corrosion. BioDur 108 alloy was designed to have corrosion resistance equivalent to or greater than the nickel-containing alloys, 22Cr-13Ni-5Mn (ASTM F1314) and 734 (ASTM F1586). The corrosion resistance levels of these alloys are superior to Type 316L alloy (ASTM F138).

Critical crevice temperatures of 50°F (10°C) were measured (per ASTM G48, Method D) in BioDur 108 alloy specimens. Critical temperatures of 41°F (5°C) were measured in identically prepared specimens of the 22Cr-13Ni-5Mn alloy. Under these test conditions, the critical temperature of the Type 316L alloy would be below 32°F (0°C). The relative corrosion resistances of BioDur 108 alloy and the comparative alloys were confirmed with anodic polarization testing in Ringer's solution at 98.6°F (37°C).

BioDur 108 alloy specimens tested passed the intergranular corrosion requirements of ASTM A262, Practice A.

Important Note: The following 5-level rating scale is intended for comparative purposes only. Corrosion testing is recommended; factors which affect corrosion resistance include temperature, concentration, pH, impurities, aeration, velocity, crevices, deposits, metallurgical condition, stress, surface finish and dissimilar metal contact.

Nitric Acid	Good	Salt Spray (NaCl)	Excellent
Sea Water	Moderate	Humidity	Excellent

Properties

Physical Properties

Density

-- 0.2760 lb/in³

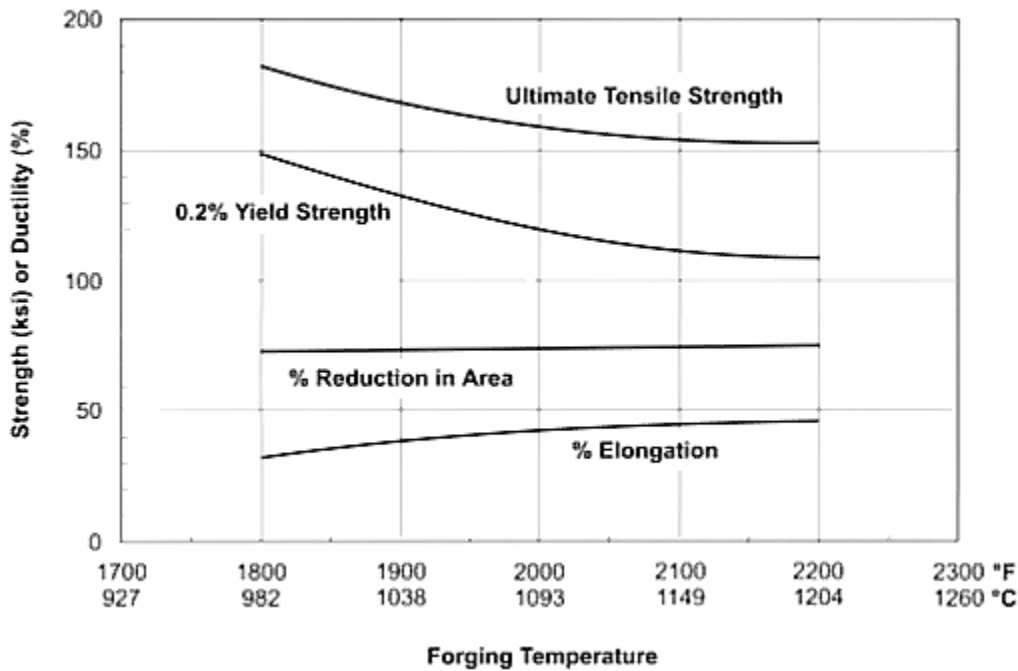
Magnetic Properties

Magnetic Permeability

-- 1.0100 Mu

Typical Mechanical Properties

Strength and Ductility vs. Forging Temperature—BioDur 108 Alloy



0.1-in (2.5 mm) Diameter Wire

% Cold Work	Ultimate Tensile Strength		Yield Strength		% Elongation	% Reduction in Area
	ksi	MPa	ksi	MPa		
(Annealed)	135	931	88	607	49	70
10	165	1138	140	965	33	69
20	195	1345	175	1207	23	68
30	225	1551	205	1413	16	64
40	245	1689	230	1586	12	60
50	270	1862	245	1689	7	53
60	292	2013	260	1793	5	45
70	308	2124	268	1848	4	35
80	320	2206	270	1862	3	23

Data represent wire cold drawn various amounts from a starting diameter of 0.1 in (2.5mm). Tests represent full wire section. Elongation values represent a gauge length of 2 in (50mm).

Tensile Properties—BioDur 108 Alloy

BioDur 108 alloy possesses high strength levels and a high work hardening rate due to its high nitrogen content. The following tables illustrate typical tensile properties in the annealed and cold worked conditions for 1 in (25mm) bar and 0.1 in (2.5mm) wire.

1-in (25 mm) Diameter Bar

% Cold Work	Ultimate Tensile Strength		Yield Strength		% Elongation in 4 X Dia.	% Reduction in Area
	ksi	MPa	ksi	MPa		
(Annealed)	135	931	85	586	52	75
10	154	1062	114	786	37	73
20	183	1262	138	952	25	68
30	217	1496	178	1227	19	63
40	251	1731	225	1551	12	59

Data represent bar cold drawn various amounts from a starting diameter of 1.0 in (25mm). Tests represent 0.505 in (12.8mm) diameter specimens machined from the bar center.

Tests of Parts Forged from Various Temperatures and Water Quenched—BioDur 108 Alloy Forgings

Forging Temperature		Yield Strength		Ultimate Strength		% Elongation in 4 X Dia.	% Reduction in Area
°F	°C	ksi	MPa	ksi	MPa		
2200	1204	107	741	157	1083	45	75
2200	1204	120	827	165	1138	43	74
2100	1149	110	759	156	1078	44	74
2000	1093	115	792	154	1061	45	73
1900	1038	147	1014	172	1185	34	73
1900	1038	131	905	172	1188	39	74
1800	982	150	1036	182	1253	33	73

Data represent hip implant parts forged from 0.625 in (16mm) diameter bar and water quenched. Tests represent 0.150 in (3.8mm) diameter specimens machined from the distal end of the forgings and tested in the as-forged condition.

Toughness

Like most austenitic alloys, BioDur 108 alloy possesses very high toughness levels. In the annealed condition, room-temperature impact energy levels for standard 10mm x 10mm Charpy V-Notch specimens would exceed the capacity of common testing machines. High nitrogen austenitic alloys exhibit a "ductile-to-brittle" transition behavior which is similar to ferritic alloys. In BioDur 108 alloy, this transition is suppressed to temperatures below 32°F (0°C). The data in hyperlink entitled "CVN Impact Test Data" represent tests of annealed BioDur 108 alloy sub-size specimens at various temperatures. Note the transition from ductile to brittle behavior as the temperature is lowered below -4°F (-20°C).

Fatigue Data:

The fatigue resistance of BioDur 108 alloy benefits from its high strength levels, since, in austenitic alloys, fatigue limit is closely related to the tensile strength. The data shown in the hyperlink entitled "RR More Rotating-Beam Fatigue Tests at Room Temperature" represents annealed BioDur 108 alloy specimens with a grain size of ASTM #5 and an Ultimate Tensile Strength of 135 ksi (930 MPa). The fatigue limit is approximately 41% of the tensile strength.

CVN Impact Test Data—BioDur 108 Alloy

Test of 5mm x 10mm Sub-Size Specimens per ASTM E23

Test Temperature		Impact Energy		Fracture Mode
°F	°C	ft-lb	J	
100	+38	100	136	Ductile Rupture
72	+22	90	122	Ductile Rupture
32	0	86	117	Ductile Rupture
5	-15	78	106	Ductile Rupture
-4	-20	79	107	Ductile Rupture
-13	-25	24	33	Mixed
-22	-30	6.5	8.8	Cleavage
-40	-40	5.5	7.5	Cleavage

RR Moore Rotating-Beam Fatigue Tests at Room Temperature—BioDur 108 Alloy

Test Stress		Percent of Ultimate Tensile Strength	Cycles to Fracture
ksi	MPa		
75	517	56%	40,000
65	448	48%	37,000
60	414	44%	224,000
57.5	396	43%	612,000
55	379	41%	23,512,000 (NF)

% of UTS values represents the test stress divided by the Ultimate Tensile Strength 135 ksi (931 MPa)

NF indicates test was terminated without the specimen fracturing.

Heat Treatment

Annealing

Annealing is accomplished in the range 1900 to 2100°F (1040 to 1150°C). Typically the alloy is annealed in the lower part of this range to preserve a fine grain size. The alloy should be rapidly cooled from the annealing temperature. This is because slow cooling through the range from 1800 to 1500°F (980 to 810°C) under some circumstances can cause precipitation of a chromium nitride phase (Cr₂N) which could adversely affect corrosion resistance and toughness. Annealing at 1950°F (1065°C) for one hour, followed by a water quench, may be used in most cases.

Heat treating BioDur 108 alloy in non-argon atmospheres results in the formation of a thin magnetic (ferritic) surface layer on the heat treated product which must be removed from the finished product.

Hardening

BioDur 108 alloy cannot be hardened by heat treatment. It must be hardened by cold working.

Workability

Forging

BioDur 108 alloy may be hot worked by procedures simulating those used for 22Cr-13Ni-5Mn (ASTM F1314) and 734 (ASTM F1586) alloys. Heat the alloy uniformly to a temperature in the range of 1900°F to 2200°F (1040°C to 1200°C) for forging. Do not forge at temperatures below 1800°F (980°C). Forgings may be air cooled or water quenched.

Parts should be annealed after forging. In some cases, water quenching after forging may circumvent the need for annealing. The effect of forging temperature on mechanical properties can be found in the hyperlinks entitled "Tests of Parts Forged from Various Temperatures and Water Quenched," and "Strength and Ductility vs. Forging Temperatures" within the Typical Mechanical Properties section of this datasheet.

Machinability

BioDur 108 alloy may be machined by procedures similar to those used for 22Cr-13Ni-5Mn (ASTM F1314) and 734 (ASTM F1586) alloys. A continuous positive cutting action should be maintained to avoid work hardening. Slow to moderate speeds, moderate feeds, and rigid tools should be considered. Tools must be kept sharp. Use a sulfurized cutting fluid, preferably of the chlorinated type.

The feeds and speeds in the following table may be considered as starting points when developing machining parameters for a specific job.

Machining

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The feeds and speeds in the following table may be considered as starting points when developing machining parameters for a specific job.

Representative Machining Parameters—BioDur 108 Alloy

Operation	Speed		Feed	
	sfm	m/min	in/rev	mm/rev
Turning - High Speed Tools:				
Single point & box tools ⁽¹⁾	55-70	17-21	0.015-0.007	0.38-0.18
Cut-off tools - 3 mm (0.125 in)	40-65	12-20	0.001	0.025
Form tools - 25 mm (1 in)	40-65	12-20	0.001	0.025
Turning - Carbide Tools:				
Single point & box tools ⁽¹⁾	225	70	0.015-0.007	0.38-0.18
Cut-off tools - 3 mm (0.125 in)	150	45	0.005	0.13
Form tools - 25 mm (1 in)	150	45	0.003	0.08
Drilling - High Speed Tools:				
6 mm (0.25 in) dia.	45-50	14-15	0.004	0.10
20 mm (0.75 in) dia.	45-50	14-15	0.010	0.25
Reaming - High Speed Tools:				
6 mm (0.25 in) dia.	65	20	0.005	0.13
20 mm (0.75 in) dia.	65	20	0.010	0.25
Reaming - Carbide Tools:				
6 mm (0.25 in) dia.	200	60	0.005	0.13
20 mm (0.75 in) dia.	200	60	0.010	0.25

⁽¹⁾ Depth of cut = 3.8 - 0.6 mm (0.150 - 0.025 in)

Weldability

BioDur 108 alloy should not be welded using fusion welding processes.

Other Information

Metallurgical Requirements

BioDur 108 alloy heats evaluated have met the metallurgical requirements pertaining to 22Cr-13Ni-5Mn alloy which are listed in section 7 of ASTM F1314. These requirements are as follows:

1. The material shall exhibit no free ferrite phase when examined metallographically at 100X magnification.
2. The microcleanness, as determined by ASTM E45, Method A, except using Plate III and Plate I, on representative billet or bar samples shall not exceed the following:

Inclusion Type	A (Sulfide)	B (Alumina)	C (Silicate)	D (Globular Oxide)
Thin	1.5	2.5	2.5	2.5
Heavy	1.5	1.5	1.5	1.5

Applicable Specifications

- ASTM F2229

Forms Manufactured

- Bar-Rounds
- Strip
- Wire-Rod
- Billet
- Wire

Technical Articles

- [Properties of an Essentially Nickel-Free Stainless Alloy for Medical Implants](#)
- [Selecting New Stainless Steels for Unique Applications](#)
- [Specialty Alloys And Titanium Shapes To Consider For Latest Medical Materials Requirements](#)
- [Unique Properties Required of Alloys for the Medical and Dental Products Industry](#)